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substances hence is non-volatile and relatively slowly absorbed by the smoker. *As the smoke pH increases above about 6.0, an increasing proportion of the total smoke nicotine occurs in "free" form, which is volatile, rapidly absorbed by the smoker, and believed to be instantly perceived as nicotine "kick."*

Id. at 2 (emphasis added). The document continues:

As a result of its higher smoke pH, the current Marlboro, despite a two-thirds reduction in smoke "tar" and nicotine over the years, calculates to have essentially the same amount of "free" nicotine in its smoke as did the WINSTON. Over the same period, with some reduction in smoke pH and about two-thirds reductions in smoke "tar" and nicotine, the calculated amount of "free" nicotine in WINSTON smoke has decreased by about two-thirds. Thus, currently the calculated amount of "free" nicotine in Marlboro smoke is almost three times the amount in WINSTON smoke.

Id. (emphasis added; underscoring in original). This document goes on to describe methods of increasing smoke pH:

Methods which may be used to increase smoke pH and/or nicotine "kick" include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, (3) use of alkaline additives, usually ammonia compounds, to the blend, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids from or add alkaline materials to the smoke, and (7) use of high air dilution filter systems. Methods 1-3, in combination, represent the Philip Morris approach, and are under active investigation.

Id. at 4.

A document entitled "Outline for Smoke pH Presentation" presents further data on the increase in pH in Marlboro cigarettes and Kool cigarettes. Finding that, as compared to RJR's Winston brand, Marlboro cigarettes had several characteristics, including alkaline stem additives and ammonia-puffed leaf, "all combining to raise smoke pH," the presentation states:

We must conclude that the difference between Marlboro and Winston must be deliberate. . . . What we are seeing and measuring fits what we know about Philip Morris and Brown and Williamson product philosophies. They appear to design products primarily to deliver optimum nicotine impact and satisfaction--aiming also at a relatively bland smoke, letting flavor fall where it will.

Another document in the series is a memorandum to RJR's Director of Marketing and Planning recommending the development of a new "youth-appeal" brand with more tar and nicotine. Colby FG, *Cigarette Concept to Assure RJR a Larger Segment of the Youth Market* (Dec. 4, 1973). See AR (Vol. 711 Ref. 47). According to the memorandum, "any desired additional nicotine 'kick' could be easily obtained through pH regulation."

When these documents were made public, RJR officials responded that the documents are not important and that subsequent studies on Marlboro showed that pH levels between 1973 and 1988 declined, while sales remained steady or increased. Weinstein H, Documents tie nicotine levels, cigarette sales, *Los Angeles Times*, A1 (May 23, 1996). See AR (Vol. 711 Ref. 18).

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2. Comments from the tobacco industry argue that ammonia compounds are added to tobacco to enhance the flavor characteristics of cigarette smoke and bind the tobacco together, but not for their effect on nicotine. The Agency disagrees with this comment. The record contains numerous internal documents that indicate that the effect of adding ammonia compounds is to change the delivery or absorption of nicotine. For instance, the Brown & Williamson's 1991 leaf blending manual states that "[a]mmonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine."⁹⁶⁹ Similarly, William Farone, the former director of applied research at Philip Morris, states that "[t]he use of ammonia chemistry was important to the industry in maintaining adequate nicotine delivery to satisfy smokers."⁹⁷⁰ The industry's assertion that the use of ammonia is simply for taste and binding cannot be reconciled with this evidence. Even if ammonia does have a flavor component, this fact does not negate the evidence in the record regarding ammonia's effect on nicotine.

The tobacco industry cites the addition of ammonia compounds to foods as evidence of ammonia's role in flavor. The use of ammonia compounds in foods, however, is not dispositive evidence of the use of ammonia compounds in tobacco, because the ammonia compounds in cigarettes are burned and inhaled rather than ingested. Moreover, one of the recognized uses for ammonia compounds in foods is "pH control," 21 CFR

⁹⁶⁹ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess., 21 (Jun. 21, 1994) (statement of David Kessler) (emphasis added). See AR (Vol. 709 Ref. 3).

⁹⁷⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13 (emphasis added). See AR (Vol. 638 Ref. 2).

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184.1133–184.1143, which is the same use of ammonia compounds described in the internal tobacco company documents.

3. Comments from the tobacco industry argue that FDA has taken a contradictory position in the Jurisdictional Analysis by finding both that cigarette manufacturers add ammonia compounds to increase the pH of tobacco and that cigarette manufacturers add acids to reduce the harshness of smoke.

FDA's positions are not inconsistent. The Jurisdictional Analysis found, based on the evidence then available, that when manufacturers use tobaccos that produce naturally high pH levels in smoke or that have naturally high nicotine contents, the manufacturers sometimes face the problem that the cigarette smoke contains too much nicotine and is too harsh. In these situations, the record indicates that manufacturers have developed ways to reduce harshness, including lowering pH. *See* Jurisdictional Analysis, 60 FR 41711–41713. In other situations, manufacturers face the opposite problem of cigarette smoke that may not deliver enough nicotine. In these latter situations, the record indicates that manufacturers will enhance nicotine deliveries, including adding ammonia compounds to raise the pH of the tobacco and the smoke, which increases the delivery of free nicotine to the smoker. *See* section II.C.4.c.

4. Brown & Williamson makes two comments regarding chemical manipulation. First, Brown & Williamson asserts that its internal documents show its knowledge that pH level does not affect nicotine delivery. Second, Brown & Williamson asserts that its internal documents show that the addition of ammonia compounds is simply a booster of smoke “impact.”

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The Agency disagrees with Brown & Williamson's characterization of its documents. Contrary to Brown & Williamson's comment, the administrative record shows that researchers working for Brown & Williamson and Brown & Williamson's parent, BATCO, have consistently understood that pH levels affect nicotine delivery. As early as 1968, BATCO researchers wrote that "[n]icotine retention appears to be dependent principally on smoke pH and nicotine content."⁹⁷¹ See sections II.C.3.c.i., II.C.3.c.iv., II.C.4.c.

In fact, one of the documents cited by Brown & Williamson contradicts its assertion. In a passage not quoted by Brown & Williamson, the document refers to the "pH dependent effect of nicotine," further underscoring the company's understanding of the relationship between pH and nicotine.⁹⁷²

The Agency does agree with Brown & Williamson that the 1991 blenders handbook links the addition of ammonia compounds to the "impact" of smoke. However, the document makes it clear that "impact" is simply a surrogate term for nicotine delivery, stating that the ammonia compounds increase "the ratio of extractable nicotine to bound nicotine in the smoke"; that "extractable nicotine contributes to the impact in cigarette smoke"; and that "this is how ammonia can act as an impact booster."⁹⁷³

⁹⁷¹ BATCO, *The Retention of Nicotine and Phenols in the Mouth* (1968), at BW-W2-11691 (emphasis added). See AR (Vol. 445 Ref. 7593).

⁹⁷² Ayres CI (BATCO), Notes from the GR&DC Nicotine Conference, in Proceedings of the Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at BW-W2-02642 (emphasis added). See AR (Vol. 14 Ref. 172).

⁹⁷³ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler). See AR (Vol. 709 Ref. 3).

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iv. Comments on Flavorings and Casings.

1. The cigarette manufacturers dispute that flavorings and casings are sometimes used to mask the unpleasant sensory characteristics of nicotine in cigarettes. The tobacco industry claims that flavorings and casings are used solely to affect the flavor and aroma of the cigarette.

The Agency agrees that flavorings and casings influence flavor. Nevertheless, the record shows that these ingredients have another use—that of masking the flavor of harsh high-nicotine tobaccos. In the Jurisdictional Analysis, the Agency cited several pieces of evidence showing that flavorings and casings are used to mask nicotine. *See* 60 FR 41711–41714. For instance, a “flavorist” for RJR wrote that “in air-cured tobaccos (cigar, burley, Maryland), the pH of smoke is generally alkaline and the flavor effect of nicotine is a ‘harshness’ which can be choking and unpleasant.”⁹⁷⁴ In these tobaccos, according to the flavorist, “the effect of nicotine is greatly modified, and the harshness is dramatically reduced. . . . by addition of sugars . . . to ‘mellow’ the smoke.”⁹⁷⁵ None of this evidence is rebutted by the cigarette manufacturers.

In addition, the statement of William Farone, the former director of applied research at Philip Morris, confirms that flavorings are used to mask the harshness of nicotine. According to Farone’s statement:

The tobacco industry found that in the manipulation of the nicotine/tar ratio, the methods used to increase the nicotine to tar ratio sometimes resulted in a cigarette that was too harsh. With a standard nicotine/tar ratio in a traditional cigarette no flavor smoothing compounds are generally needed to produce a

⁹⁷⁴ Leffingwell JC, Nitrogen components of leaf and their relationship to smoking quality and aroma, *Recent Advances in Tobacco Science*, vol. 2, at 9. *See* AR (Vol. 28 Ref. 450).

⁹⁷⁵ *Id.*

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palatable cigarette. The higher tar levels in traditional cigarettes mask the harshness of nicotine and the associated compounds produced in higher nicotine to tar ratios. A low tar cigarette with a higher nicotine/tar ratio than a traditional cigarette could be very harsh due to the lack of sufficient specific tar components to mask the nicotine and related basic compounds. *To overcome the harshness due to the increased burley in the blend, the industry used flavor "smoothers."*⁹⁷⁶

Thus, the evidence in the record supports the finding in the Jurisdictional Analysis that the cigarette industry sometimes uses flavorings to mask the harshness of nicotine in cigarettes with nicotine-rich tobacco blends.

2. The cigarette manufacturers cite the use of menthol in cigarettes as evidence that they do not use flavorings to mask the effects of nicotine. According to the industry, menthol is not used to mask the effects of high-nicotine tobaccos because menthol cigarettes generally have nicotine yields that are lower than or equal to regular cigarettes.

The Agency rejects this argument. The evidence before the Agency indicates that flavorings like cocoa, sugars, and licorice, which produce acids in smoke, are used to mask the bitterness or harshness of nicotine. *See* Jurisdictional Analysis 60 FR 41711–41714. The evidence does not indicate that menthol is used to mask harshness of tobacco. Consequently, the data presented by the industry on menthol is irrelevant to whether other flavorants are used to mask nicotine.

v. Comments on the Consistency of Nicotine Deliveries.

1. The cigarette manufacturers argue that the ability to produce cigarettes with uniform and consistent levels of nicotine is not evidence of any "intended use." They

⁹⁷⁶ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 14-15 (emphasis added). *See* AR (Vol. 638 Ref. 2).

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assert that blending to achieve consistency is a common practice among manufacturers that make consumer goods from agricultural products.

However, the remarkable degree of consistency in nicotine deliveries achieved by the manufacturers is especially relevant to the issue of the manipulation and control of nicotine. As discussed in section II.C.4.e.iii., above, the manufacturers' precise control over nicotine deliveries refutes the manufacturers' assertion that "the companies do not independently 'control' for or 'manipulate' the nicotine content in any of their blends."⁹⁷⁷ Moreover, the manufacturers' precise control over nicotine deliveries is consistent with—and corroborates—the Agency's finding that manufacturers intend that cigarettes will be used for pharmacological purposes. As discussed in the Jurisdictional Analysis, an FDA laboratory study showed that nicotine delivery varies so little from lot to lot of cigarettes that it equals or exceeds the degree of control exercised by pharmaceutical companies over the active ingredients in prescription drugs.⁹⁷⁸ The manufacturers' precise control over nicotine deliveries enable the industry to ensure that consumers can use cigarettes to satisfy addiction or to obtain other pharmacological effects.

vi. Comments on Breeding.

The comments of the cigarette industry claim that the cigarette manufacturers do not manipulate nicotine through plant breeding or agronomic practices. While the comments make several valid points on tangential issues, they do not affect the basic conclusions made in the Jurisdictional Analysis.

⁹⁷⁷ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. V, at 66. See AR (Vol. 535 Ref. 96).

⁹⁷⁸ FDA, Center for Drug Evaluation and Research, Division of Drug Analysis, Memorandum on Analysis of Packages of Cigarettes (Apr. 4, 1994). See AR (Vol. 29 Ref. 487).

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1. Regarding FDA's contention that American-grown tobaccos have had increasingly high levels of nicotine since the mid 1950's, the comments fault FDA for singling out the years 1955 and 1980 for comparison.

The Agency reported in the Jurisdictional Analysis the change in nicotine content between 1955 and 1980 because those were the years analyzed in the paper by DeJong cited by the Agency.⁹⁷⁹ The Agency agrees that the more recent data from the North Carolina Official Variety Trials, as submitted by the comments, show that nicotine content of leaves from that area has leveled off since 1980, and that the last 17 years appear to show a decrease in nicotine levels.⁹⁸⁰ The Agency does not agree, however, that it should have compared nicotine levels in the 1950's to nicotine levels in 1989, as suggested by the cigarette manufacturers. Unusually low nicotine levels were recorded in 1989 when compared with the five years preceding and succeeding it.

Other articles and information support the Agency's contention that the nicotine content of domestic tobacco increased from the 1950's to 1980. For example, one study cited by a comment concluded that nicotine levels "changed dramatically" from the mid-1950's to the early 1980's and ascribed the increase to changes in production practices.⁹⁸¹

⁹⁷⁹ DeJong DW, The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint. *Tabak Journal International*, May 1985;376-383. See AR (Vol. 27 Ref. 401).

⁹⁸⁰ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 18. See AR (Vol. 535 Ref. 96).

⁹⁸¹ Bowman DT, Wernsman EA, Corbin TC, *et al.*, Contribution of genetic and production technology to long-term yield and quality gains in flue-cured tobacco, *Tobacco Science* 1984;28:30-35, at 34-35. See AR (Vol. 535 Ref. 96, vol. IV.A).

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In addition, Earl Wernsman of North Carolina State University told the Agency that nicotine levels have increased over the past 30 years.⁹⁸²

The Agency, however, does not agree with the industry's claim, that "FDA's reliance on the DeJong data, together with the Agency's total failure to acknowledge contrary data from equally or more authoritative sources, reflects a general strategy of selective and biased citation from the scientific literature."⁹⁸³ In fact, both sets of data reflect rising nicotine levels in tobacco from the mid 1950's through 1980.

2. The cigarette industry comments assert that the manufacturers have rejected high-nicotine tobacco crops produced during drought years. According to the industry, this rejection of high-nicotine crops shows that the manufacturers do not seek to manipulate nicotine through breeding high-nicotine tobaccos.

The Agency does not agree that any reliable inference can be drawn from the rejection of tobacco crops in drought years. This evidence establishes only that nicotine content can on occasion rise too high for the manufacturers' use. The Agency has never maintained that nicotine levels could not reach excessive levels. To the contrary, as discussed in the Jurisdictional Analysis, the Agency recognizes that too much nicotine in a cigarette can make the cigarette too harsh, requiring the use of flavors and casings to mask the harshness. *See* 60 FR 41712–41713.

3. The cigarette industry comments raise a number of issues regarding FDA's discussion of the Minimum Standards Programs (MSP's). The comment claims that

⁹⁸² Memorandum of Mar. 22, 1994, teleconference, from Murray M, to Wernsman E (Mar. 23, 1994). *See* AR (Vol. 256 Ref. 3459).

⁹⁸³ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 9. *See* AR (Vol. 535 Ref. 96).

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“FDA has mischaracterized the nature, purpose and effect of the . . . MSP’s by claiming that the MSP’s were designed to ensure that nicotine levels did not fall below a specified level,” and that by “minimizing the role of the USDA, tobacco breeders, and State Extension-Research Services, FDA mischaracterizes the tobacco industry’s participation in these programs as ‘controlling.’”⁹⁸⁴ The comment argued that the cigarette manufacturers do not control the MSP’s, that the MSP’s are not designed to maintain nicotine above a specified level, and that the MSP’s prevent the introduction of high-nicotine varieties into cultivation.

The Agency does not find compelling any of the arguments raised by the comment that were intended to dispute the two most significant findings of the Agency regarding MSP’s: that they are used to ensure that nicotine levels do not fall below a specified level, and that the cigarette manufacturers are active participants in the program.

The comment points out that there are a variety of purposes of the MSP’s, and argues that therefore it is incorrect for FDA to claim that their purpose is “to ensure that nicotine levels in marketed tobacco do not fall below specified levels.”⁹⁸⁵ FDA agrees that the MSP’s have purposes in addition to controlling nicotine levels. However, the fact remains that the MSP’s help ensure that nicotine levels in marketed tobacco do not fall below the level in acceptable tobacco varieties. DeJong made this point clear when he wrote that “the first minimum standards programme was initiated in 1964. . . . Discount or *low-nicotine cultivars had previously been declared outside the price support system.*”⁹⁸⁶

⁹⁸⁴ *Id.* at 18-19 (emphasis added).

⁹⁸⁵ *Id.* at 21-22.

⁹⁸⁶ DeJong DW, The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint, *Tabak Journal International*, May 1985:382 (emphasis added). See AR (Vol. 27 Ref. 401).